DRAFT

HUMAN SUBJECTS RESEARCH PROTECTION POLICY (Domain 10)

Policy Statement: The City of Bloomington Division of Public Health will comply with federal law in the ethical collection of data involving the use of human subjects and will seek Institutional Review Board (IRB) approval as needed.

Rationale: BPH is committed to protecting an individual's privacy and to prevent any untoward health consequences or breaches of confidentiality as a result of interventions, evaluations or assessment activities (hereafter referred to as activities) implemented by BPH staff or with BPH clients. Therefore, it is the policy of BPH that any new activity or changes in current activities involving human subjects or client records be reviewed by the management team prior to implementation and at regular intervals as necessary. When an activity is classified as research involving human subjects, BPH will seek IRB review with a collaborating research partner to comply with ***Title 45 Code of Federal Regulations Part 46, 2009 revision (45 CFR 46)*** in the protection of human subjects. Note: the BPH management team does not serve as an IRB.

The purpose of these guidelines is to assist Public Health staff to:
1) use available research to guide evidence based practice
2) contribute to the evidence by participating in research
3) design assessments and evaluations that meet ethical principles for use of human subjects
4) obtain review by an Institutional Review Board (IRB) when appropriate

We recognize the value to the agency and benefit to the community through participation in research. In so doing, we seek to both contribute to and apply the evidence base for public health practice. We also rely on the evidence-based guidance of practice to assure programs and services provided are shown to have the desired outcomes. An evidence based approach is key to assuring the most effective and efficient use of limited resources.

Community health assessments and program evaluations involve gathering data from people through surveys, interviews, focus groups, and other methods. Whenever we are collecting or using data from individuals, we need to consider several issues related to human subjects. We need to identify whether our work falls in the category of research, requiring formal review by an IRB, or whether it is public health practice. Regardless of whether it is research or practice, we also must consider how we will protect the autonomy and privacy of participants, avoid exploitation of vulnerable populations, maximize benefits, and minimize risk.

One way to distinguish between research and public health practice is in the intended uses of the work:

1. If the main purpose of the project is to produce generalizable knowledge (applies to people other than the ones studied) to improve public health practice and the benefits extend beyond the study participants from whom the information was collected, it is considered ***research.***

2. If the main purpose is to prevent disease or injury, or improve sudden or current, on-going public health program or services AND the knowledge gained will primarily benefit the participants, the project may be considered ***non-research*** (i.e., public health practice).

Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation

1. What is the **purpose** of the project? Does the purpose justify the use of human subjects? What question(s) are you trying to answer? How will the information be used? Who is the audience for the results?

2. What **methods** will you use to gather data? Are these methods appropriate for the question(s) you're trying to answer? Are you using a validated data collection instrument? If not, how will you pre-test your questions? What sample size and response rate is needed to make good inferences from the data?

3. What **population group** are you seeking for the project? How will you access/locate people to participate? Consider the principle of justice: why are you collecting/using data from this group?

4. What are the potential **risks** and burdens of the project to participants? Consider time, stress, possible intrusion into personal or sensitive issues, emotional discomfort, breach of confidentiality, etc.

5. What are the potential **benefits** of the project? To participants? To the health department? To the community? Do the benefits outweigh the risks to participants?

6. How will you handle **confidentiality** of personal or sensitive information? Will participation be anonymous, confidential, or neither? How will data be stored? Who will have access to data and for how long? Are personal identifiers needed? For what purpose? When will they be removed from assessment information and destroyed?

7. How will you obtain **informed consent** from people to participate in the project? A consent form should be simply worded (at a reading level appropriate to the audience) and cover the following elements: · The purpose of the project and what participants would be asked to do

· Person(s) and group(s) conducting the project

· Expected duration of participation

· Benefits that can be expected from participation, if any

· Potential risks or harms that may occur

· How confidentiality of information will be maintained and any limits to confidentiality

· Statement that participation is voluntary, that refusal to participate will not result in a loss of services or benefits, and that participation can be stopped at any point during the project without penalty

· Information on who to contact for answers to questions about the project

PH Assessment and Evaluation Projects Considered Research (PH Samples)

· Meningococcal Disease Case-Control Study of High School Students (study of high school students with meningococcal disease and several unaffected classmates to identify associated risk factors)

Exempt criteria for research projects: MDH http://www.health.state.mn.us/irb/exempt.html

The kinds of research that are exempt according to the federal regulations governing the IRB (45 CFR 46) are listed below. The exemption criteria do **not** apply to research involving prisoners, pregnant women, fetuses, or in-vitro fertilization.

-Research involving the collection or study of existing data, documents, or records, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

-Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those

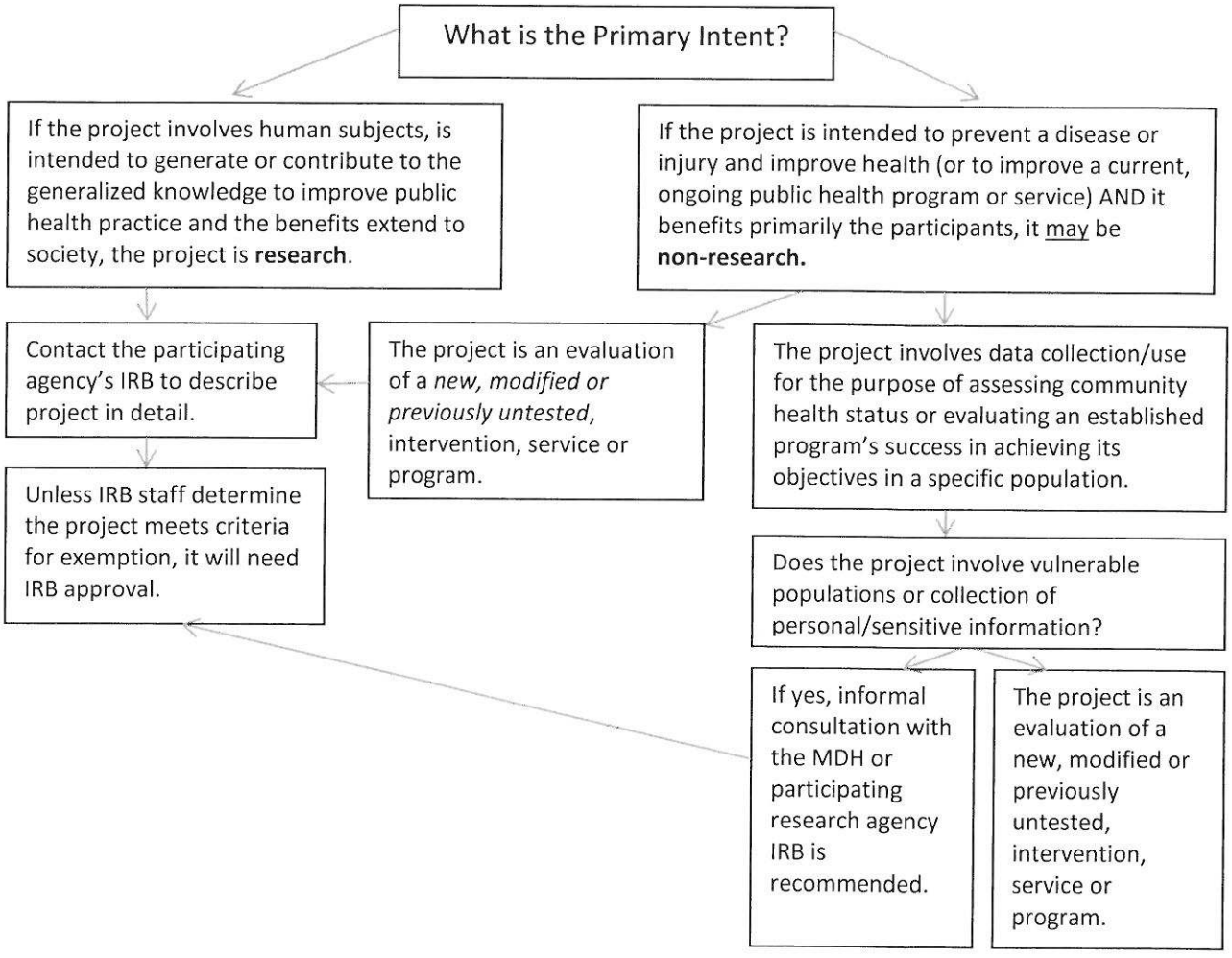
programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

PH Assessment and Evaluation Projects Considered Non-Research (PH Samples)

- Client Satisfaction Surveys for public health programs (examples include clinics, WIC, family home visiting, etc. which are used to identify specific program performance and improvement areas to better serve clients' needs)
- MN Student Survey (school-based survey of students in grades 5,8,9,and 11 done every three years)
- SHAPE - Survey of the Health of All the Population and the Environment (south suburban Hennepin County populations surveyed and assessed every 4 years)
- Community Health Needs Assessment

DECISION TREE

Is it Research or Public Health Practice?



When in doubt, consult with an IRB. An IRB review of a project may be required if it involves the collection/use of data from people and:

· It is funded or sponsored by the federal or state government

· It will produce information that is applicable beyond the immediate population from whom it was collected

· It's an evaluation of a new, modified, or previously untested intervention, service, or program

· It involves the collection of sensitive or personal information

· It involves vulnerable populations (e.g., children, pregnant women, etc.)

The Minnesota Department of Health Institutional Review Board (IRB) site has information that can be of help. http://www.health.state.mn.us/irb/index.html Here is the link to an application for IRB review: http://www.health.state.mn.us/irb/application.pdf.

Procedures:

1. The BPH management team will assess internally which projects need an IRB review or determination. Because BPH does not have an internal IRB and cannot make a formal IRB determination, the Minnesota Department of Health IRB will be consulted for formal review of research projects. When appropriate, other IRBs from different research facilities may be used depending on the project lead.
2. The BPH management team will utilize the **Decision Tree** and the **Questions to Consider When Using Human Participants in Public Health Assessment and Evaluation** shown above.
3. If in doubt, the BPH management team will consult with the MDH IRB.
4. The management team will document whether the project is considered research or not with a date and PH Administrator's signature.

Evaluation:

This policy and procedure will be reviewed annually by the BPH management team. The objectives will be reviewed and updated as needed. Examples of meeting each of the objectives will be discussed.

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PH Administrator Date